

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : PAUL STARK, et al.
Divisional of Serial No. : 09/488,103
Filed January 20, 200 Group Art Unit : 1615
Filed : Herewith Examiner : Robert Joynes
Title: MULTIPARTICULATE BISOPROLOL FORMULATION

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97 and 1.98**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 CFR §1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached Forms PTO-1449 and PTO-892 and/or listed herein and which the Examiner may deem relevant to patentability of the claims of the above-identified application.

These prior art documents were also submitted in Information Disclosure Statements filed on June 20, 2002 and January 13, 2003 (copies attached) in the parent application Serial No. 09/488,103.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

If necessary, the paper should be considered as a petition for consideration of the Information Disclosure Statement under 37 C.F.R. §1.97(d)(2) and that the petition fee set forth in 37 C.F.R. §1.17(i) in accordance with 37 C.F.R. §1.97(d)(3) should be charged to Deposit Account No. 05-1323 (Docket #100338.54684C1).

Respectfully submitted,

Date April 1, 2004



Samir Elamrani
Registration No. 43,601

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Notice of References Cited

Application/Control No.

09/488,103

Applicant(s)/Patent Under
Reexamination
STARK ET AL.

Examiner

Robert M. Joynes

Art Unit

1615

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number	Date	Name	Classification	
		Country Code-Number-Kind Code	MM-YYYY			
	A	US-5137733	08-1992	Noda et al.	424	497
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number	Date	Country	Name	Classification	
		Country Code-Number-Kind Code	MM-YYYY				
*	N	WO 98/32426	07-1998	WIPO	Busetti et al.	A61K	9/36
	O						
	P						
	Q						
	R						
	S						
	T						

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited

Application/Control No.

09/488,103

Applicant(s)/Patent Under
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Art Unit

1615

Page of

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
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	E	US-			
	F	US-			
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	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Handbook for Pharmaceutical Excipients, Second Edition, Polymethacrylates, pp. 362-66, 1994.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Paul STARK et al.) Prior Group Art Unit: 1615
)
Cont. Application of Serial No.:) Prior Examiner: R. Joynes
09/488,103)
)
RCE Filed: June 20, 2002)
)
For: Multiparticulate Bisoprolol)
Formulation)
Commissioner for Patents
Washington, DC 20231

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO 1449. This Information Disclosure Statement is being filed prior to the issuance of a first Office Action on the merits.

Copies of the listed documents, including any copending patent applications, are attached.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the

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documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 20, 2002

By: 

Sean Myers-Payne
Reg. No. 42,920

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INFORMATION DISCLOSURE CITATION

Atty. Docket No.	08680.0001-00000	Appln. No.	09/488,103
Applicant	Paul STARK et al.		
Filing Date	January 20, 2000	Group:	1615

U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	6,303,144 B1	10/16/01	Omura	424	457	
	6,270,805 B1	8/7/01	Chen et al.	424	497	
	6,214,385 B1	4/10/01	Heinicke et al.	424	497	
	6,190,692 B1	2/20/01	Busetti et al.	424	451	
	6,033,687	3/7/00	Heinicke et al.	424	497	
	5,891,474	4/6/99	Busetti et al.	424	490	
	5,834,024	11/10/98	Heinicke et al.	424	497	
	5,834,023	11/10/98	Chen	424	497	
	5,830,503	11/3/98	Chen	424	480	
	5,788,987	8/4/98	Busetti et al.	424	480	

FOREIGN PATENT DOCUMENTS

Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
98/32425	July 30, 1998	PCT	A61K 9/28	9/00, 9/48	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

J. K. Ghali et al, "Metoprolol CR/XL in Female Patients with Heart Failure: Analysis of The Experience In Metoprolol Extended-Release Randomized Intervention Trial in Heart Failure (MERIT-HF)," Circulation, April 2, 2002, Vol. 105, No. 13, pgs 1585-1591.
X. Deroubaix et al., "Comparative Bioavailability of a Metoprolol Controlled Release Formula and a Bisoprolol Normal Release Tablet after Single Oral Dose Administration in Healthy Volunteers," International Journal of Clinical Pharmacology and Therapeutics, February 1996, Vol. 34, No. 2, pgs. 61-70.
G.L. Plasker et al., "Controlled Release Metoprolol Formulations. A review of their Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Use In Hypertension and Ischaemic Heart Disease," Drugs, March 1992, Vol. 43, No. 3, pgs. 382-414.
S.P. Glasser et al., "Circadian Heart Rate Response to Chronotherapy Versus Conventional Therapy in Patients with Hypertension and Myocardial Ischemia," Clinical Cardiology, July 2000, Vol. 23, No. 7, pgs. 524-529.

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	08680.0001-00000	Appln. No.	09/488,103
Applicant	Paul STARK et al.		
Filing Date	January 20, 2000	Group:	1615

	A. C. Ross et al., "Chronopharmaceutical Drug Delivery From a Pulsatile Capsule Device Based on Programmable Erosion," Journal of Pharmacy and Pharmacology, Aug. 2000, Vol. 52, No. 8, pgs. 903-909.
	M.H. Smolensky et al., "Medical Chronobiology: Concepts and Applications," American Review of Respiratory. Disease, June 1993, Vol. 147, No. 6, pgs. S2-S19.
	G.E. D'Alonzo et al., "Chronophysiologic Determinants of Asthma," Annals New York Academy of Science, 1991, Vol. 618, pgs. 123-139.
	M.H. Smolensky et al., "Chronopharmacology and Chronotherapy of Cardio-Vascular Medications: Relevance to Prevention and Treatment of Coronary Heart Disease," American Heart Journal, 1999, Vol. 137, No. 4, pgs. S14-S24.
	M.C. Cohen et al., "Meta-Analysis of the Morning Excess of Acute Myocardial Infarction and Sudden Cardiac Death," American Journal of Cardiology, 1997, Vol. 79, pgs. 1512-1515.
	W.J. Elliott, "Circadian Variation in the Timing of Stroke Onset: A Meta-Analysis," Stroke, May 1998, Vol. 29, No. 5, pgs. 992-996.
	R. Manfredini et al., "Circadian Variation in Spontaneous Rupture of Abdominal Aorta," The Lancet, Feb. 1999, Vol. 353, pgs. 643-644.
	M.T. Johstone et al., "The Pathophysiology of the Onset of Morning Cardiovascular Events," American Journal of Hypertension, April 1996, Vol. 9, No. 4, Part 3, pgs. 22S-28S.
	M.W. Millar-Craig et al., "Circadian Variation of Blood-Pressure," The Lancet, April 1978, Vol. 1, No. 8068, pgs. 795-797.
	J.A. Staessen et al., "Nocturnal Blood Pressure Fall on Ambulatory Monitoring in a Large International Database," Hypertension, January 1997, Vol. 29, No. 1, Part 1, pgs. 30-39.
	W. J. Elliott, "Circadian Variation in Blood Pressure Implications for the Elderly Patient," American Journal of Hypertension, February 1999, Vol. 12, No. 2, Part 2, pgs. 43S-49S.
	H. Sternberg, "Altered Circadian Rhythm of Blood Pressure in Shift Workers," Journal of Human Hypertension, May 1995, Vol 9, No. 5, pgs. 349-353.
	I. Kawachi et al., "Prospective Study of Shift Work and Risk of Coronary Heart Disease in Woman," Circulation, December 1, 1995, Vol. 92, No. 11, pgs. 3178-3182.
	H. Boggild et al., "Shift Work, Risk Factors and Cardiovascular Disease," Scandinavian Journal of Work, Environment & Health, April 1999, Vol. 25, No. 2, pgs. 85-99.
	A. F. Khoury et al., "The Early Morning Rise in Blood Pressure Is Related Mainly to Ambulation," American Journal of Hypertension, June 1992, Vol. 5, No. 6, Part 1, pgs. 339-344,
	W. J. Elliott et al., "Drug Delivery Systems For Antihypertensive Agents," Blood Pressure Monitoring, 1997, Vol. 2, No. 1, pgs. 53-60.
	S. K. Gupta et al., "The Effect of Food, Time of Dosing, and Body Position on the Pharmacokinetics and Pharmacodynamics of Verapamil and Norverapamil," The Journal of Clinical Pharmacology, 1995, Vol. 35, No. 11, pgs. 1083-1093.

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	08680.0001-00000	Appln. No.	09/488,103
Applicant	Paul STARK et al.		
Filing Date	January 20, 2000	Group:	1615

	W.B. White et al., "Nocturnal Dosing of a Novel Delivery System of Verapamil for Systemic Hypertension," The American Journal of Cardiology, August 1995, Vol. 76, pgs. 375-380.
	K. Kario et al., "Nocturnal Fall of Blood Pressure and Silent Cerebrovascular Damage in Elderly Hypertensive Patients," Hypertension, January 1996, Vol. 27, No. 1, pgs. 130-135.
	S. S. Hayreh et al., "Nocturnal Arterial Hypotension and Its Role in Optic Nerve Head and Ocular Ischemic Disorders," American Journal of Ophthalmology, May 1994, Vol. 117, pgs. 603-624.
	W.B. White et al., "Comparison of Effects of Controlled Onset Extended Release Verapamil at Bedtime and Nifedipine Gastrointestinal Therapeutic System on Arising on Early Morning Blood Pressure, Heart Rate, and the Heart Rate-Blood Pressure Product," The American Journal of Cardiology, February 1998, Vol. 81, pgs.424-431.
	R.B. Anderson et al., "Physical Symptoms Distress Index," Archives of Internal Medicine, April 1999, Vol. 159, pgs. 693-700.
	W. H. Frishman et al., "Comparison of Controlled-Onset, Extended-Release Verapamil With Amlodipine and Amlodipine Plus Atenolol on Exercise Performance and Ambulatory Ischemia in Patients With Chronic Stable Angina Pectoris," The American Journal of Cardiology, February 1999, Vol. 83, pgs 507-514.
	H.R. Black et al., "Rationale and Design for the Controlled ONset Verapamil INvestigation of Cardiovascular Endpoints (CONVINCE) Trial," Controlled Clinical Trials, August 1998, Vol. 19, No. 4, pgs. 371-387.
	H.R. Black et al., "Baseline Characteristics and Early Blood Pressure Control in the CONVINCE Trial," Hypertension, January 2001, Vol. 37, No. 1, pgs. 12-18.

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609, draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

PATENT
Customer No. 22,852
Attorney Docket No. 08680.0001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Paul STARK et al.) Group Art Unit: 1615
Application No.: 09/488,103) Examiner: Robert M. JOYNES
Filed: January 20, 2000)
For: MULTIPARTICULATE)
BISOPROLOL FORMULATION)

Commissioner for Patents
Washington, DC 20231

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO-1449. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final Action, Quayle Action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), please charge the fee of \$180.00 to our Deposit Account 06-0916 for submission of this Information Disclosure Statement as specified by Section 1.17(p).

Copies of the listed documents are attached. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed

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documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claims in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Please charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: January 13, 2003

By: Sean Myers Payne
M. Todd Rands
Reg. No. 46,249 Reg. No. 42,920

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INFORMATION DISCLOSURE CITATION

Atty. Docket No.	08680.0001	Appln. No.	09/488,103
Applicant	Paul STARK et al.		
Filing Date	January 20, 2000	Group:	1615

U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	6,358,944	3/19/02	Lederman <i>et al.</i>	514	220	
	6,350,398	2/26/02	Breitenbach <i>et al.</i>	264	129	
	6,284,800	9/4/01	Broder <i>et al.</i>	514	652	
	6,264,917	7/24/01	Klaveness <i>et al.</i>	424	9.52	
	6,228,864	5/8/01	Smith <i>et al.</i>	514	288	
	6,221,368	4/24/01	Breitenbach <i>et al.</i>	424	400	
	6,162,467	12/19/00	Miller <i>et al.</i>	424	468	
	6,150,424	11/21/00	Breitenbach <i>et al.</i>	514	772.5	
	6,120,802	9/19/00	Breitenbach <i>et al.</i>	424	464	
	6,068,855	5/30/00	Leslie <i>et al.</i>	424	468	
	6,051,253	04/18/00	Zettler <i>et al.</i>	424	465	
	6,001,391	12/14/99	Zeidler <i>et al.</i>	424	467	
	5,980,882	11/9/99	Eichman	424	78.12	
	5,965,163	10/12/99	Miller <i>et al.</i>	424	468	
	5,939,099	8/17/99	Grabowski <i>et al.</i>	424	488	
	5,897,910	4/27/99	Rosenberg <i>et al.</i>	427	2.14	

FOREIGN PATENT DOCUMENTS

Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
EP 0 463 877	1/2/92	Europe	A61K	9/54	
WO 98/26767	6/25/98	WIPO	A61K	9/50	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Co-pending U.S. Application No. 10/225,543, filed August 22, 2002.
Co-pending U.S. Application No. 10/294,693, filed November 15, 2002.
Dorow <i>et al.</i> , Effects of Single Oral Doses of Bisoprolol and Atenolol on Airway Function in Nonasthmatic Chronic Obstructive Lung Disease and Angina Pectoris, <i>Eur. J. Clin. Pharmacol.</i> , 31(2):143-7: 1986.

INFORMATION DISCLOSURE CITATION

OMB No. 0651-0011

Atty. Docket No. 08680.0001	Appln. No. 09/488,103
Applicant Paul STARK et al.	
Filing Date January 20, 2000	Group: 1615

U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	Bailliant <i>et al.</i> , Effects of Bisoprolol on Local Vascular Resistance, <i>Eur Heart J</i> , 8 Suppl M:87-93: 1987.					
	Haffner <i>et al.</i> , A Metabolic Assessment of The Beta ₁ Selectivity of Bisoprolol, <i>J. Hum. Hypertens.</i> , 6(5):397-400, 1992.					
	Horikiri <i>et al.</i> , Pharmacokinetics and Metabolism of Bisoprolol Enantiomers in Humans, <i>J. Pharm. Sci.</i> , 87(3): 289-294, 1998.					
	Janka <i>et al.</i> , Influndence of Bisoprolol on Blood Glucose, Glucosuria, and Haemoglobin A ₁ in Noninsulin-Dependent Diabetics, <i>J. Cardiovasc. Pharmacol</i> , 8 Suppl 11:S96-9: 1986.					
	Kim, <i>et al.</i> , Chiral Separation of β -Blockers after Derivatization with (-)- α -Methoxy- α -(trifluoromethyl)phenylacetyl Chloride by Gas Chromatography, <i>Arch. Pharm. Res.</i> , 24(5):402-6, 2001.					
	Kitaori, <i>et al.</i> , CsF in Organic Synthesis. The First and Convenient Synthesis of Enantiopure Bisoprolol by Use of Glycidyl Nosylate, <i>Tetrahedron Lett.</i> , 39(20), 3173-3176, 1998.					
	Klockow <i>et al.</i> , Studies on The Receptor Profile of Bisoprolol, <i>Arzneimittelforschung</i> , 36(2):197-200, 1986.					
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	Schliep <i>et al.</i> , Antagonistic Effects of Bisoprolol on Several β -Adrenoceptor-Mediated Actions in Anaesthetized Cats, <i>Eur. J. Pharmacol.</i> , 123(2):253-61, 1986.					
	Schnabel <i>et al.</i> , Binding Properties of β -Blockers at Recobinant β_1 -, β_2 -, and β_3 -Adrenoceptors, <i>J. Cardiovasc. Pharmacol.</i> , 36(4):466-71, 2000.					
	Wellstein <i>et al.</i> , Reduction of Exercise Tachycardia in Man after Propranolol, Atenolol and Bisoprolol in Comparison to Beta-Adrenoceptor Occupancy, <i>Eur. Heart J.</i> , 8(Suppl. M):3-8, 1987.					

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce